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(71) Applicants
H. G. Wallace Limited
(Great Britain),
Whitehall Road,
Colchester, Essex
(72) Inventor
Henry George Wallace
(74) Agents
Frank B. Dehn and Co.,
Imperial House, 15/19
Kingsway, London
WC2B 6UZ

(54) **Catheter guide**

(57) A guiding device for facilitating the insertion of a catheter or other tubular surgical device into a subcutaneous tunnel comprises a rod or tube having a hand grip 2 at the proximal end and, at the distal end, a detachable tip 4, 7, 8 or 15 for passing smoothly through the subcutaneous tissues.

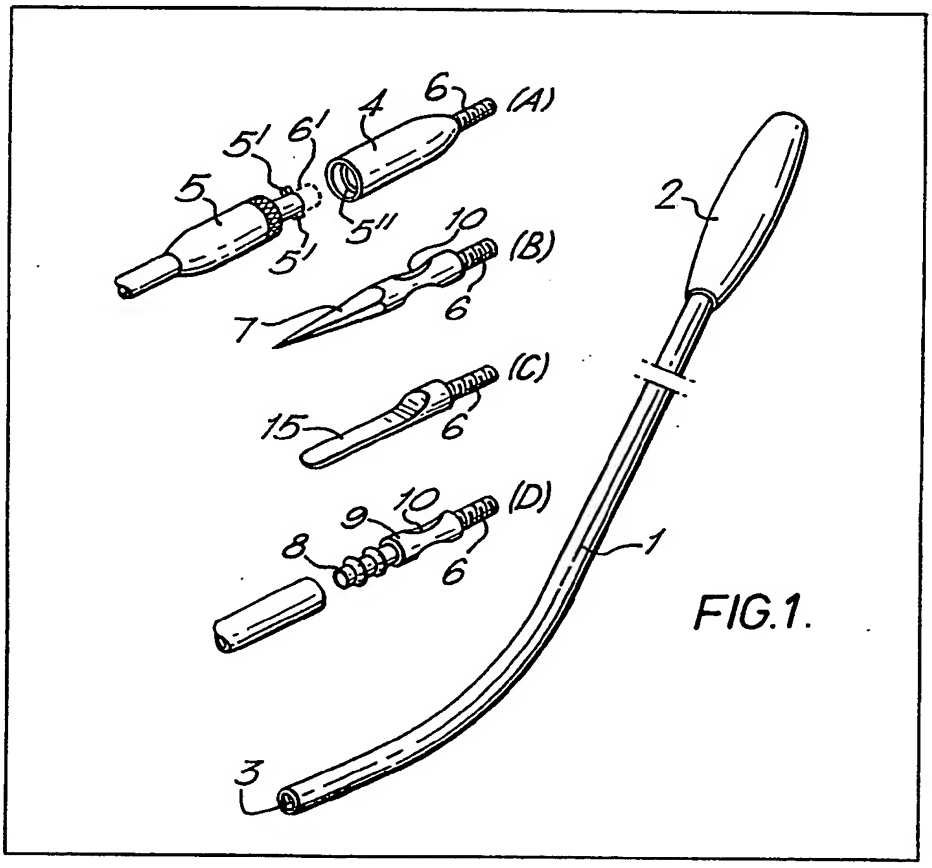

FIG.1.

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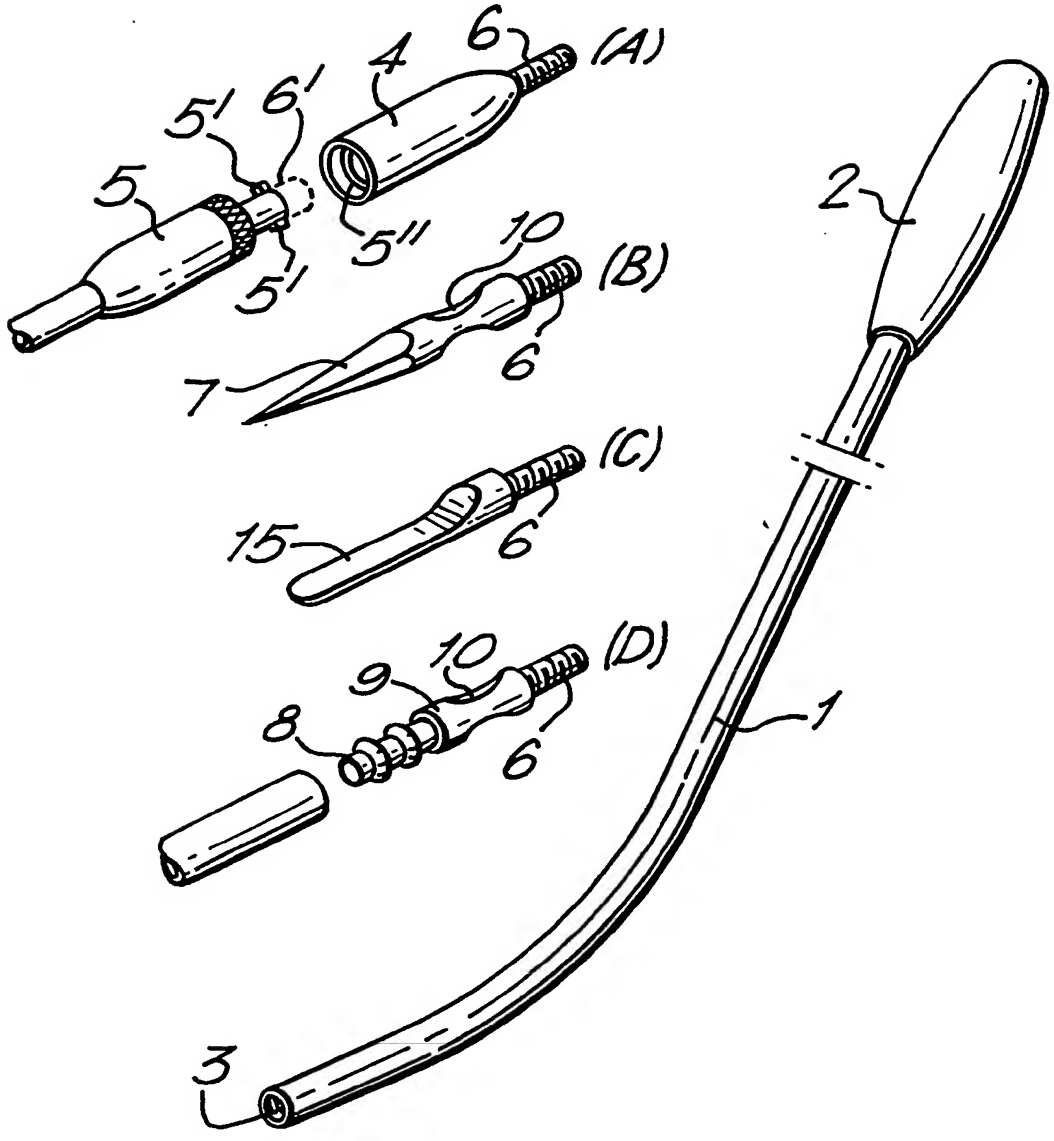


FIG. 2.

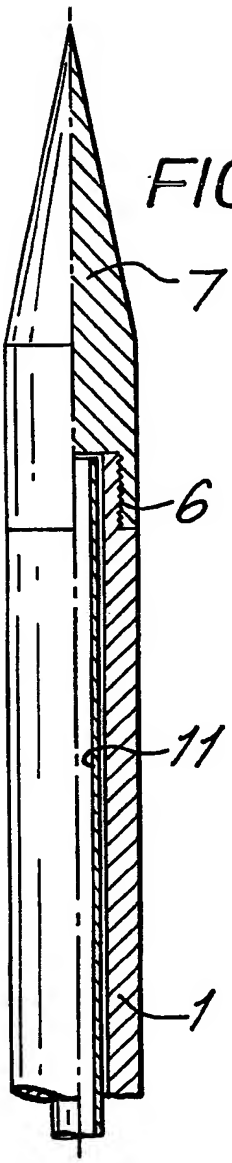
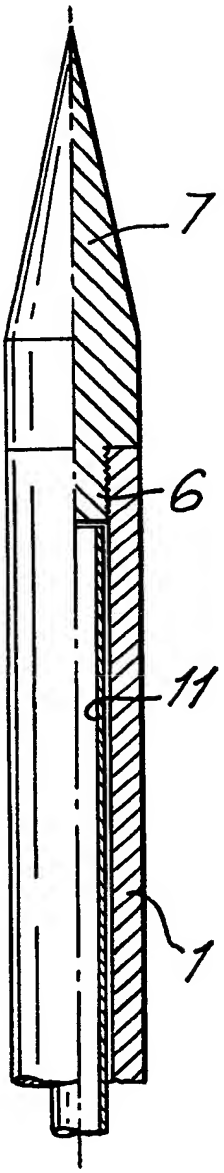


FIG. 3.



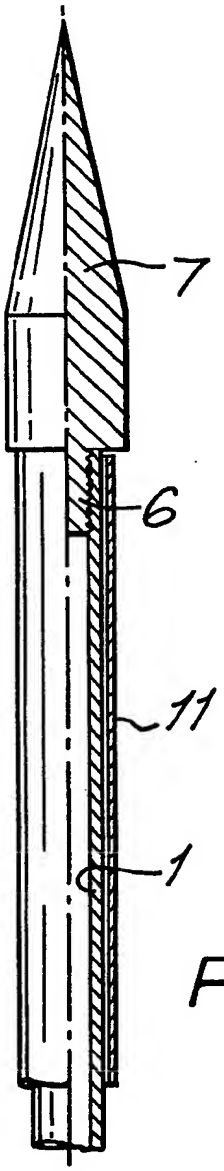


FIG. 4.

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FIG.5.

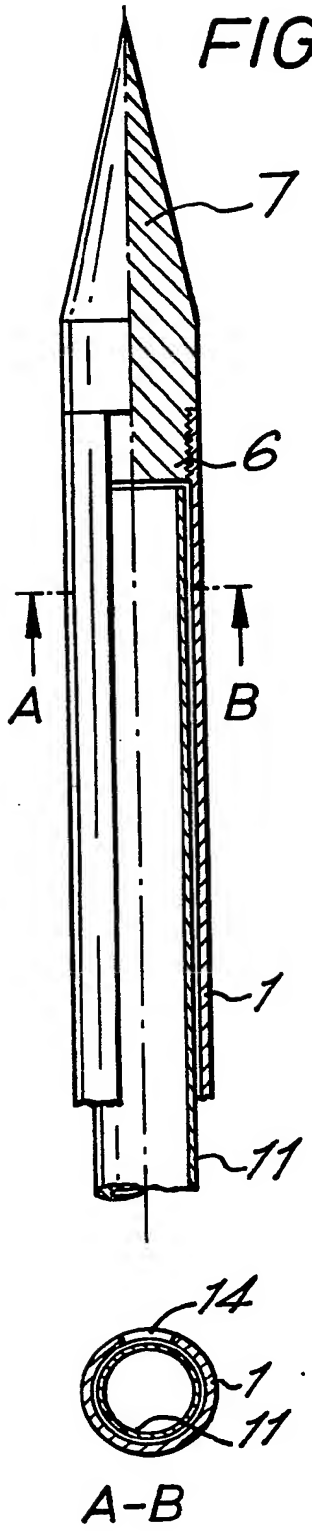
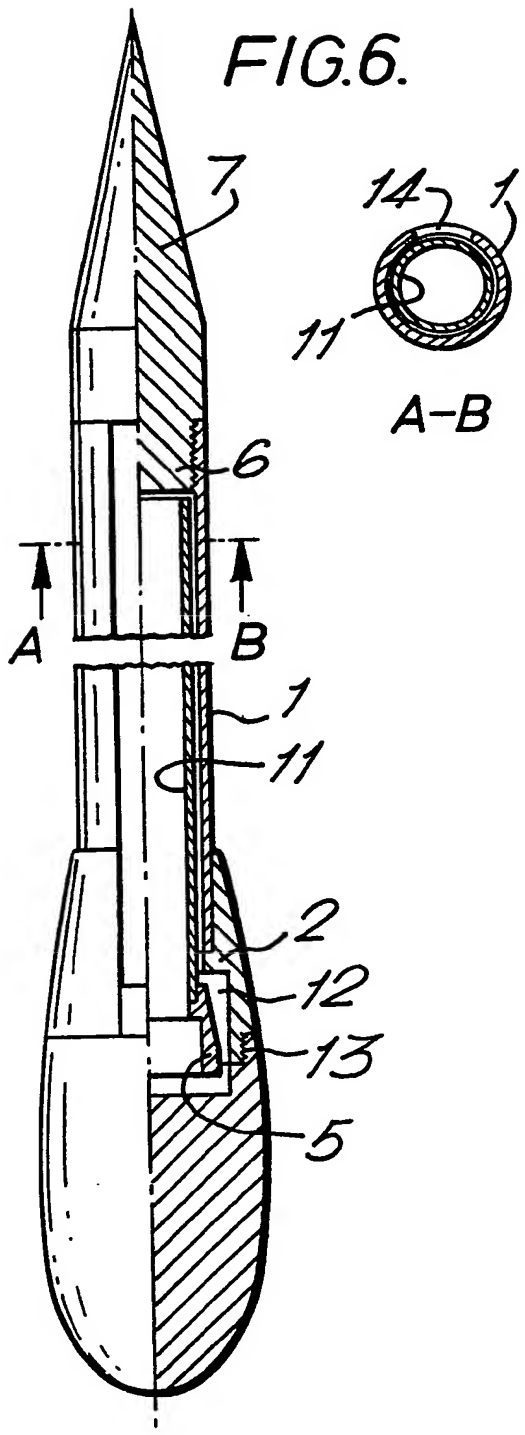


FIG.6.



SPECIFICATION

Improvements in surgical devices

This invention relates to a guiding device for the insertion, especially for the tunnelling, of catheters.

The introduction of tubular surgical devices such as cannulae or catheters into body cavities always involves a high risk of infection at the point of entry or exit of the device from the tissue. Here there is a wound, which allows bacteria direct access to the circulating blood. The risk becomes even higher when the device has to remain *in situ* for a long time, e.g. weeks or months as must always occur when the patient requires continuous treatment, for example in the case of leukaemia or cancer therapy, in the case of peritoneal dialysis, e.g. C.A.P.D. (continuous ambulant peritoneal dialysis), or in the case of total parenteral feeding.

When the catheter is positioned intravascularly, it is introduced directly into a vein (e.g. the *vena subclavia*) percutaneously after previously clearing the way by means of an incision, because by this means unwanted movements of the device are minimised and it is easily fixed in position on the patient. In this way a long term access to the central venous system is created. An additional danger here, however, is that unwanted air may be sucked in by the pumping action of the heart causing air embolism.

For these reasons, in recent years the so called "tunnelling" technique has been developed. With this technique, the free end of the catheter is not permitted to leave the blood vessel or body cavity, e.g. the peritoneam, directly but it is routed for a considerable distance (e.g. 40 cm in the case of the *vena subclavia* and in the case of a peritoneal catheter, about 6—12 cm) underneath the skin through an artificially created tunnel. In this way, externally originating infection cannot invade the blood vessel or the blood cavity. It has in fact been definitely proved that the subcutaneous tissue presents a natural barrier against infections, and in this way, so long as the catheter material can be tolerated by the tissue, the risk of infection is substantially reduced.

One method is to introduce the tube via a surgically prepared tunnel.

The catheter or other device can now be inserted into the tunnel in one of two ways. Either it is pushed, in the first step, into the tunnel and then is directed into its final position in the deep tissue, e.g. a peritoneal cavity (the so called "one-way technique"); or in the first step the distal end is inserted into the body cavity, and then as a second step the free (or proximal) end is drawn backwards into the tunnel, i.e. the second step works — so to speak — from the middle of the tube outwards. The latter method ("two-way t chniqu ") is particularly appropriate to catheters with integral couplings. The end coupling of a catheter generally has a wider diameter than the catheter tubing itself, in order to facilitate connection. The catheter coupling may either be demountable, e.g. a push fit, or it may be permanently joined to the catheter during manufacture.

Both procedures however entail risk. If a flexibl tube is pushed into a tunnel, a hollow stiff guide made of metal or plastic is required (such as a sharp tip or trocar and an introducing cannula) whereby the problem arises as to how the guide is removed, especially if the coupling, e.g. for connection to an infusion set, forms an integral part of the catheter, and has a larger diameter than the latter. With the second method, the coupling on the catheter tube must be removed if the tube is to be drawn backwards through the tunnel, or it must be drawn into a capsule, so that the coupling does not snag in the tissue and thereby cause trauma. A detachable (e.g. push-fitted or screwed on) coupling presents other problems, including contamination. On the one hand, a coupling which is a push fit is too liable to come apart; on the other hand, a screw thread would not find a sufficient grip in the very flexible material of the tube. But even as an integral part of the tube the coupling, by reason of its greater diameter, is of course equally an obstacle to pushing the tube through the tunnel, and is likewise prone to cause trauma.

From the preceding discussion it follows that the "tunnelling" technique is in practice usually undertaken by surgeons working without purpos - designed equipment.

An object of the invention is therefore to make available a guiding device which facilitates insertion of a catheter or other tubular surgical device into a tunnel, and in so doing will as far as possible avoid or reduce the above mentioned disadvantages.

According to the invention there is provided a guiding device for facilitating the insertion of a catheter or other tubular surgical device into a subcutaneous tunnel comprising a rod or tube having a hand grip at the proximal end and, at the distal end, a detachable tip for passing smoothly through the subcutaneous tissues.

The guiding device may be made e.g. in metal or hard plastic and a distal portion thereof is preferably slightly curved, e.g. in the last third of its length. The device may also be flexible or bendable to suit any specific surgical situation. At the proximal end of this appliance we provide a hand grip, optionally at least in part removable, which grip preferably is elongated and rounded off (for instance cylindrical with a rounded end, or of ovoid form).

The distal end is provided with means for the attachment of the tip. Such means may e.g. be an internal screw thread or other hollow space, or a projecting plug with an external screw thread.

For use with the device there are in fact several accessory tips which are principally required for the "two-way t chnique" described above, and which, for example, by means of a plug provided with a thread on its proximal end, can be screwed into the aforesaid distal end of the guiding device. These accessory tips will be more fully described

her aft r in relation to their various contributions to the tunnelling process.

For example, by screwing or otherwise attaching a sharp tip, e.g. a metal tip or so-called trocar, to the guiding device, or more preferably a dissector tip of flattened and rounded form, it is possible to cut a tunnel in a simple manner, and simultaneously to bring the guiding device into position for the purpose of attachment to the catheter (i.e. the "one-way technique"), so that the surgical creation of a tunnel becomes unnecessary.

Should the insertion of the catheter into the tunnel take place in accordance with the second technique mentioned above, i.e. by drawing the catheter backwards via an integral coupling, then this may advantageously be done by pushing the catheter coupling into a housing member open at the distal end which in turn is provided with a threaded plug at its proximal end, which plug can be screwed into the distal end of the guiding device that has already been pushed through the tunnel. The housing member should have a streamlined or rounded, elongated shape in order that it can be easily drawn through the tunnel, without its bulk causing any damage.

If the catheter tube does not possess an integral coupling means, then the procedure of drawing it backwards through the tunnel can likewise be facilitated by the guiding device of our invention.

For this purpose, a coupling member is carried on the proximal end of a thickened central portion a threaded plug which can be screwed into the distal end of the guiding device, and on its distal end presents a suitable means for releasably attaching to a flexible catheter tube, for example a plug provided with means for increasing its frictional engagement within the lumen of a catheter, e.g. one or more circumferential ribs.

Should the above mentioned first method of tunnelling (the "one-way technique") be employed, which consists of first inserting the catheter tube into the tunnel and then bringing it into a desired position (e.g. in a blood vessel), then this can be done for catheters without couplings in a particularly simple and elegant manner with the help of the guiding device in accordance with the invention provided with a sharp tip (preferably of metal) on the distal end.

In one procedure the catheter is pushed into a correspondingly dimensioned hollow space within the guiding device and then — as described above — a sharp tip is screwed on to the distal end. The tip is preferably hollow and has an internal diameter sufficient to accommodate the catheter tube, so that the latter can be push d a little way inside it and projects beyond th distal end of the actual guiding device.

Using the guiding device prepared in this manner, the tunnel can now be bored directly through the tissue. Then the tip is unscrewed and the catheter is advanced in that its distal end is free of the guiding device. The end can then be firmly held while the guide is drawn back through the tunnel.

A disadvantage of this method is that both the tip and the tubular guiding device must be relatively wide, as the catheter must certainly fit into the hollow tip and this in turn must fit into the guiding tube.

This disadvantage will be avoided if one employs a tip with a solid plug, and lets the catheter terminate short of this plug (and thus proximal to the end of the tube of the guiding device). In this case, after unscrewing the tip, the catheter must be advanced further, beyond the guiding device so that it can be held firmly while the guiding device is drawn back.

On the other hand, however, a narrower guiding tube and a slimmer or standard tip can be used.

A further variation of the "one-way technique" is to draw the full length of the catheter (without any coupling means) over the guiding device, so that the latter lies inside. In this case, a tip must be screwed on as a perforator which is wider than the guiding device approximately to the extent of the thickness of the wall of the catheter, so that the catheter can be pushed through the tunnel in the clearance provided by the tip and does not itself snag or roll up on the body tissue. Here also, the tip is subsequently unscrewed, the catheter is held firmly, and the guiding device is drawn back through the tunnel.

It is however possible to form the guiding device in the manner of a gutter in such a way that it is not circumferentially continuous, but contains a slot through which the catheter tube can be peeled out after tunnelling. The catheter is then laid into the guiding device, and is thereupon inserted into the tunnel together with the guide. After completing the insertion procedure both ends of the catheter are grasped and lifted, in such a way that the catheter can be manipulated out of the guide through the slot and the guide can be removed.

It is even possible, using the "one-way technique", to insert the catheter with an integral attachment or coupling. For this, the handle of the slotted guiding tube device described above is constructed to admit the catheter coupling means. In this embodiment the handle can either be completely or partially removed (e.g. screwed off), and/or it is provided with a slot along at least part (e.g. one third) of its length, which slot may be aligned with that in the guide to permit removal of the coupling from the guide. The technique of freeing the catheter together with the coupling is in accordance with the procedure previously described.

The guiding device according to the invention will generally be supplied sterilisable and reusable, but may be packaged in a hermetically sealed container or wrapping, e.g. plastics foil, and sterilised *in situ* by heat, radiation or chemical sterilants. After its first use the device can be cleaned and resterilised, or in some instances may be treated as disposable.

Various embodiments of our invention will now be described, by way of illustration only, with

reference to the accompanying drawings wherein:

Fig. 1 shows a perspective view of a tubular guiding device. Inset are shown various accessories for attachment to the distal end;

Figs. 2 to 5 are plan views, partially in section, of the distal end of guiding devices according to the invention having a sharp tip mounted thereon and a catheter inside or outside said device;

Fig. 6 is a plan view, partially in section, of a slotted guiding device having an attached handle and a catheter within said device and handle.

Turning now to Fig. 1, there is shown a guiding device in the form of a tube 1 slightly curved in the distal third of its length, with elongated hand grip 2 on the near end, and internal screw thread 3 on the distal end.

The elements 4, 7, 8 and 15 are accessory members which can be attached to the guiding tube by means of a plug 6 with external screw thread.

The housing 4 (inset A) is open at the distal end for the admittance of a catheter end coupling 5 comprising Luer lock ears 5' and at its proximal end is provided with a screwed plug 6. The housing has an internal thread 5" to anchor the coupling releasably therein.

A removable plug 6' is shown temporarily sealing the end of the catheter.

Below at inset 8 is shown a detachable sharp metal tip 7 to serve as perforator, which similarly can be fixed to the guiding device 1 by means of a screwed plug 6. The tip is provided with two opposed concave gripping surfaces 10.

However the sharply pointed tip is liable to cause some trauma and we prefer the dissector tip, 15 (inset C) having a flattened and rounded end. The action of the dissector tip is to dilate rather than cut the tissue, with benefit to the patient.

At inset D is shown a coupling member 8 for connecting the free end of a catheter without an end coupling to the guiding device. The central portion 9 is thickened and provided with two opposed concave gripping surfaces 10. It carries at one end a plug 6 with an external thread, and at the other end a plug with two circumferential ribs for frictional engagement with the lumen of a catheter.

Fig. 2 shows a tubular guiding device 1 with a sharp tip 7 screwed on to it. The connecting plug 6 of the tip is hollow and contains the distal end of a plain catheter tube 11, which in this manner projects beyond the distal end of the guiding tube.

Fig. 3 shows an alternative construction in which the connecting plug 6 of the tip is solid, and the catheter 11 lying inside the guide terminates proximal to this plug.

Fig. 5 shows an internal guide tube 1, onto which the catheter 11 has been threaded. The tip 7 employed is wider than the guiding tube, and forms a shoulder to provide the walls of the catheter with clearance during the tunnelling process.

Fig. 5 shows a guiding device in the form of a slotted tube 1 from which the catheter 11 lying within can be lifted out following the tunnelling procedure. The slot 14 is shown more clearly in the inset section taken along the line A—B.

In Fig. 6 the guiding tube is slotted longitudinally as in Fig. 5 and as shown in the inset section along A—B. In addition is provided with a hand grip 2 slotted longitudinally in the distal third of its length, which possesses a hollow space 12 adapted for the admittance of a cathet r coupling (or attachment). The proximal portion of the grip may be unscrewed at screw threads 13 to expose the catheter end coupling 5 and allow its removal from guiding device. It will be appreciated that the coupling 5 has a diameter too large to allow its passage through the longitudinal slot.

CLAIMS

1. A guiding device for facilitating the insertion of a catheter or other tubular surgical device into a subcutaneous tunnel comprising a rod or tube having a hand grip at the proximal end and, at the distal end, a detachable tip for passing smoothly through the subcutaneous tissues.

2. A device according to claim 1 wherein a distal portion of said rod or tube is longitudinally curved.

3. A device according to claim 1 wherein said rod or tube is bendable to suit a specific surgical situation.

4. A device according to any of claims 1—3 wherein said detachable tip is flattened and rounded to form a dissector tip.

5. A device according to any of claims 1—3 wherein said detachable tip is sharply pointed.

6. A device according to any of claims 1—3 wherein said detachable tip comprises a housing open at the distal end for receiving the coupling of a catheter.

7. A device according to any of claims 1—3 wherein said detachable tip comprises a plug for insertion into a catheter tube, said plug being provided with means for increasing its frictional engagement within the lumen of a catheter.

8. A device according to any of claims 1—5 wherein said tube is dimensioned to accommodate a catheter internally.

9. A device according to claim 8 wherein said tube is provided with a longitudinal slot to enable removal of said tube from the catheter.

10. A device according to claim 9 wherein said hand grip is hollow to accommodate a catheter coupling and is completely or partially detachable and/or provided with a slot to enable removal of said coupling from th device.

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